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The Standard Evaluation Procedure (SEP) for Field Testing for Pollinators is a guidance document primarily intended for Agency reviewers and the regulated industry who assess pesticide hazards to bees. The SEP is also intended to provide information to the general public indicating how the Agency uses toxicity data to determine if field testing for pollinators is required. As such, it is designed to supplement Subdivision L of the Pesticide Assessment Guidelines: Hazard Evaluation - Nontarget Insects. This SEP provides an Introduction, Discussion of Test Standards, Reporting Requirements, and a section on Reviewer Evaluation.

The SEP for Field Testing for Pollinators is only one of a number of SEP's available through the National Technical Information Service as a supplement to Subdivisions E and L of the Pesticide Assessment Guidelines.

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

FIELD TESTING FOR POLLINATORS

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STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.

John W. Melone, Director
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FIELD TESTING FOR POLLINATORS

I. INTRODUCTION

A. When Required

This study may be required under the following conditions:

- Data from the honey bee subacute feeding study (§ 141-4, currently reserved) indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);
- Data from residual toxicity studies indicate unusually extended residual toxicity; or
- Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity such as the ability to cause reproductive or chronic effects.

B. Purpose

As this field test will be required only on a case-by-case basis and will be conducted in response to some specific problem, it may be designed to answer any number of questions concerning pesticide hazard to bees. These questions will be determined during consultation between the registrant and the Agency.

C. Test Material

The test product shall be a typical end-use product.

II. MATERIALS AND METHODS: TESTING STANDARDS/RECOMMENDATIONS

A. Acceptable Protocols

Information useful in developing a test protocol may be obtained from the following references. It should be noted, however, that any testing conducted to satisfy this requirement should be preceded by consultation with the Agency.

Atkins, E.L., Jr., L.D. Anderson, D. Kellum and K.W. Neuman. 1976. Protecting Honeybees from Pesticides. Univ. of Calif., Div. of Agric. Sciences, Leaflet 2883. 14 pp.

Robinson, W.S., and C.A. Johansen. 1978. Effects of Control Chemicals for Douglas-Fir Tussock Moth Orgyia pseudotsugata (McDonnough) on Forest Pollination (Lepidoptera: Lymantriidae). Wash. St. Ent. Soc. "Melanderia" 30:9-56.

B. Test Organisms

1. Acceptable Species

Testing will be conducted on the species of concern. Pollinators of economic importance in the U.S. include the honey bee (Apis mellifera), alfalfa leafcutting bee (Megachile rotundata), and alkali bee (Nomia melanderi).

C. Test Conditions

The test conditions for conducting an actual field test should resemble the conditions likely to be encountered under actual use of the product. Specifically, the pesticide should be applied to the site at the rate, frequency, and method specified on the label.

III. REPORTING REQUIREMENTS

A. Test Material

The composition of the test material must be stated; percent active ingredient (a.i.) must be reported.

B. Observations

Reporting on observations should include the following:

° Frequency, duration, and method of observation; and

° Detailed description of the nature, incidence, time of occurrence, severity, and duration of all observed toxic effects.

C. Data Analysis

The appropriate method of analysis will vary with the problem being investigated; methods should be determined through consultation with the Agency.

IV. REVIEWER EVALUATION/STUDY INTERPRETATION

A. Acceptability

The reviewer should identify each aspect of the reported procedure that is inconsistent with the protocol agreed upon during pre-test consultation. The significance of these deviations must be determined. The number of deviations and their severity will determine the validity of the study and the interpretation of the results.

B. Evaluation of Results

The reviewer should indicate what the results were and how much information can be drawn from them.

The data from this study will reflect the specific problem being investigated. The reviewer should use this information, along with whatever other information is available (e.g., proposed use, application instructions, use rates) to determine the nature of the hazard to pollinators. Data from this test may be used to develop bee precaution statements for the product label, or to impose certain restrictions on the use of the product.

C. Conclusions

1. Categorization of Results

The significance of inconsistencies in the test procedures must be determined by the reviewer so that the results of the test can be categorized as to their usefulness in a risk assessment. Categories are described as:

- Core: All essential information was reported and the study was performed according to recommended protocols. Minor inconsistencies with standard methodologies may be apparent, but the deviations do not detract from the study's soundness or intent. Studies within this category fulfill the basic requirements of Part 158 of the regulations and are acceptable for use in a risk assessment.

- Supplemental: Studies in this category are scientifically sound; however, they were performed under conditions that deviated substantially from recommended protocols. Results do not meet regulatory requirements; however, the information may be useful in a risk assessment.

- Invalid: These studies provide no useful information. They may be scientifically unsound, or they were performed under conditions that deviated so substantially from recommended protocols that the results will not be useful in a risk assessment.

2. Rationale

To support a supplemental or invalid category, the reviewer must list and explain all test conditions that deviate from recommended protocols.

3. Repairability

If any or all of the deviations can be reexamined and found acceptable (i.e., the study category can be upgraded), the reviewer

also discusses this. Usually, to upgrade a study, additional information must be requested.

D. Observation of Toxic Signs and Behavioral Responses

Observation of toxic signs and behavioral responses, other than death, may be useful for evaluating the hazard of the test material.

E. Comments on Statistics

Statistics presented in the report should be verified. Any deviation should be noted and explained if possible.